Package leaflet: Information for the user

Lidbree 42 mg/mL intrauterine gel
lidocaine

Read all of this leaflet carefully before you start giving this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Lidbree is and what it is used for
2. What you need to know before you use Lidbree
3. How to use Lidbree
4. Possible side effects
5. How to store Lidbree
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1. What Lidbree is and what it is used for

Lidbree is a numbing gel used to prevent pain from gynaecological procedures, such as placement of contraceptive devices into the womb (uterus) and sampling biopsies for laboratory evaluation at gynaecological examinations, in adults and adolescents from 15 years of age. It contains the active substance lidocaine, an amide type local anaesthetic (that numbs the parts of the body it is applied to).

How Lidbree works

After application of gel it takes 2 to 5 minutes before the genital area (the mucosa) is numb. The gel has been shown to reduce the pain during gynaecological procedures and up to at least 30 minutes after the procedure. After 1 hour the pain relieving effect has worn off.

2. What you need to know before you use Lidbree

Do not use Lidbree if you are allergic to lidocaine or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

For cervical and intrauterine use only. After use of the gel for the placement of intrauterine contraceptives (intrauterine contraceptive devices, IUDs), in some cases bleeding and/or exceptional pain may occur after difficult insertions. In such cases, physical examination and ultrasound investigation should be performed immediately to exclude perforation of the uterus (womb) or cervix (neck of the womb). On average, 1 in 1000 placements of IUDs was reported to cause a perforation.

Tell the person who is going to give you Lidbree:
- If you have an abnormal heart rhythm (partial or complete heart conduction block) because local anaesthetics may affect it.
- If you are being treated for abnormal heart rhythm [with so called Potassium channel blockers or class III antiarrhythmics (e g amiodarone)] because the cardiac effects may increase.

- If you have a condition called acute porphyria (a condition running in the family, related to one of the proteins in your blood). Lidocaine may cause attacks of porphyria and should only be prescribed to patients with acute porphyria on strong or urgent indications
- If you are of poor general health.

Children and adolescents
Children below 15 years should not receive this medicine because of the risk of side effects due to high blood concentrations of lidocaine.

Other medicines and Lidbree
Tell your doctor or healthcare professional if you have recently taken any other medicines containing lidocaine, or medicines against irregular heart rhythm (anti-arrhythmics, such as mexiletine or anti-arrhythmics class III such as amiodarone), since their effects on the heart would add to the effect of lidocaine.

Pregnancy and breast-feeding
Based on long-term experience, use of lidocaine during pregnancy is not known to cause adverse effects on the newborn child.

Lidocaine may enter the mother's milk, but in such small amounts that there is generally no risk of an effect on the breast-fed newborn. Breast-feeding may therefore continue in the case of treatment with Lidbree.

Lidocaine is not known to have an effect on fertility.

Driving and using machines
Lidbree has no or negligible influence on the ability to drive and use machines.

Lidbree contains macrogolglycerol ricinoleate (castor oil polyoxyl), and butylated hydroxytoluene (E 321)
Macrogolglycerol ricinoleate may cause severe allergic reactions.
Butylated hydroxytoluene (E 321) may cause irritation to the mucous membranes.

3. How to use Lidbree

The numbing gel will be applied by your doctor or midwife (nurse) step by step starting from the entrance of the womb (uterus).

Use in adolescents
Low-weight adolescents, below 30 kg body weight, should receive a reduced dose.

If you are given more Lidbree than you should be given
With the recommended doses this is not expected, however, inform your doctor or nurse immediately if you experience numbness of your lips or tongue, light-headedness, ringing in the ear (tinnitus) or have difficulty speaking or seeing properly (visual disturbances) as this could be the first signs of high blood concentrations of lidocaine. Sometimes muscle twitching or trembling (tremors) or a pause in your breathing (apnoea) may occur and your doctor or nurse should then promptly ensure you are breathing properly (airway support) and give you anticonvulsants.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects experienced after use of Lidbree for placement of contraceptives in the womb (uterus) are similar to those experienced with placement without Lidbree.

The possible side effects are:
- **Very common side effects** (more than 1 in 10 people): nausea (feeling sick).
- **Common side effects** (may affect up to 1 in 10 people): dizziness, headache, unpleasant sensations in the belly.

Reporting of side effects
If you get any side effects, talk to your doctor or midwife (nurse). This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

Ireland
HPRA Pharmacovigilance
Website: https://www.hpra.ie

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Lidbree

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date (month-year) which is stated on the carton and syringe. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Lidbree contains
- The active substance is lidocaine. Each mL intrauterine gel contains 42 mg lidocaine.
- The other ingredients are:
  - Macrogolglycerol ricinoleate (castor oil polyoxyl)
  - Poloxamer (containing butylated hydroxytoluene (E 321))
  - Sodium ascorbate (E 301)
  - Hydrochloric acid for pH adjustment
  - Sodium hydroxide for pH adjustment
  - Water for injection

What Lidbree looks like and contents of the pack

The product is an intrauterine (into the womb) gel that is sterile, clear to almost clear, slightly brown-yellow viscous liquid at room temperature containing 42 mg/mL of lidocaine. The formulation shows reversible temperature-dependent gelation and is a gel at body temperature (thermogelling). Lidbree 42 mg/mL intrauterine gel is provided in a sterile 10 mL prefilled syringe packed in a blister. A sterile applicator with a Luer lock that fits with the prefilled syringe is provided in a separate bag within the carton. 8.5 mL can be extruded (pushed out) from the syringe-applicator.
Pack size: 1×10 mL intrauterine gel in pre-filled syringe.

Lidbree Applicator label symbols

				
Catalogue number	Batch code	Do not use if package is damaged	Do not re-use	CE-marking
				
Manufacturer	Use-by date	Sterilized using irradiation	Consult instructions for use	

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Gedeon Richter Plc.
Gyömrői út 19-21.
Budapest H-1103
Hungary

Manufacturer:
Recipharm Karlskoga AB
Björkbornsvägen 5
SE691 33 Karlskoga
Sweden

Gedeon Richter Plc.
Gyömrői út 19-21.
Budapest H-1103
Hungary

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria:	Lidbree 42 mg/ml Gel zur intrauterinen Anwendung
Belgium:	Lidbree 42 mg/ml gel voor intra-uterien gebruik
	Lidbree 42 mg/ml gel intra-utérin
	Lidbree 42 mg/ml Gel zur intrauterinen Anwendung
Bulgaria:	Lidbree 42 mg/ml intrauterine gel
Croatia:	Lidbree 42 mg/ml intrauterini gel
Cyprus:	Lidbree
Czech Republic:	Lidbree
Denmark:	Lidbree
Estonia:	Lidbree
Finland:	Lidbree 42 mg/ml Geeli kohtuun
France:	LIDBREE 42 mg/ml gel intra-utérin
Germany:	Lidbree 42 mg/ml Gel zur intrauterinen Anwendung
Greece:	Lidbree
Hungary:	Lidbree 42 mg/ml intrauterin gél
Iceland:	Lidbree
Ireland:	Lidbree
Italy:	Lidbree
Latvia:	Lidbree 42 mg/ml gimdos ertmės gels
Lithuania:	Lidbree 42 mg/ml intrauterīnais gelis
Luxembourg:	Lidbree 42 mg/ml gel intra-utérin

Netherlands:	Lidbree 42 mg/ml gel voor intra-uterien gebruik
Norway:	Lidbree
Poland:	Lidbree
Portugal:	Lidbree 42 mg/ml gel intrauterino
Republic of Malta:	Lidbree 42 mg/mL intrauterine gel
Romania:	Lidbree 42 mg/ml gel cu cedera intrauterină
Slovakia:	Lidbree 42 mg/ml intrauterini gel
Slovenia:	Lidbree 42 mg/ml intrauterinný gél
Spain:	Lidbree 42 mg/ml gel intrauterino
Sweden:	Lidbree 42 mg/ml intrauterin gel
United Kingdom:	Lidbree 42 mg/mL intrauterine gel

This leaflet was last revised in April 2022.

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The following information is intended for healthcare professionals only:

For cervical and intrauterine use only.
After use of Lidbree, in case of difficult insertion and/or exceptional pain or bleeding during or after insertion, physical examination and ultrasound should be performed immediately to exclude perforation of the uterine corpus or cervix, as with effective topical anaesthesia the patient might not react with pain in case of a perforation.

Thermogelling formulation: Lidbree is a thermogelling, preservative-free local anaesthetic viscous liquid. The formulation forms a gel when temperature increases to body temperature, and thereby remains adhered to the mucosal tissues in the cervical canal, and the uterus (minimising leakage that would occur with a liquid formulation).

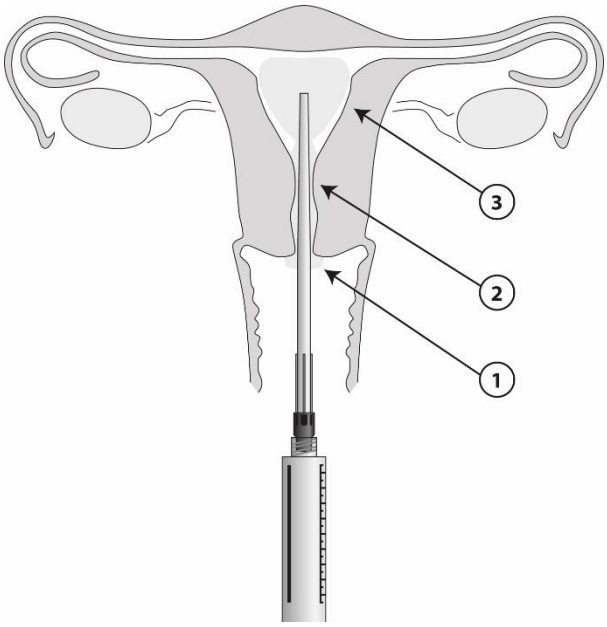
Method of Application and Dose
When administered, Lidbree should be a liquid. If it has formed a gel, it should be placed in a refrigerator until it becomes a liquid again. The air bubble visible in the syringe will then move if the syringe is tilted.

Assemble the product stepwise and apply the viscous liquid by use of the co-packed sterile applicator:

1) Check the appearance of the syringe while tilting it. The air bubble in the syringe will move when tilted if the product is in liquid state ready for use. If the air bubble does not move the product has formed a gel – then place in refrigerator until it becomes a liquid again.
2) Connect the plunger rod and applicator to the syringe and ensure they are tightly connected.

3) Extrude the air bubble and fill the applicator with gel by cautiously pushing the plunger of the syringe.
4) Use the applicator centimetre scale for positioning the Lidbree formulation.

With the applicator in place, 8.5 mL gel can be delivered from the syringe. One mL contains 42 mg lidocaine. Apply the gel stepwise (1 to 3) as illustrated in the figure.



Cervical procedures
1) Apply 2 to 3 mL in a thick layer to the portio using the sterile applicator.
2) Apply 3 mL into the cervical canal 5 minutes before start of procedure using the applicator.

Intrauterine procedures
1) Apply 1 to 2 mL to the anterior lip of the portio using the sterile applicator.
2) Apply 2 to 3 ml into the cervical canal using the applicator. Wait 2 minutes for the onset of effect at the inner meatus.
3) Thereafter insert the applicator into the uterine cavity and introduce 3 to 5 mL, 5 minutes before the procedure. The applicator is marked with a centimetre scale. A smaller volume can be administered, e.g. in nulliparous patients, if the patient experiences discomfort before the whole volume has been given.

A single intrauterine dose should not exceed a total of 10 mL. Discard any unused contents.

Paediatric population from 15 years of age

In low-weight adolescents below 30 kg body weight the dose should be proportionally reduced, and a single dose should not exceed the maximum recommended parenteral dose (6 mg/kg lidocaine hydrochloride, corresponding to 5.2 mg/kg lidocaine base in Lidbree, i.e. 1.2 mL Lidbree per 10 kg body weight). In adolescents with a body weight of 30 kg the maximum dose of Lidbree is 3.6 mL in total.

Duration of effect
The gel has been shown to reduce the pain during gynaecological procedures and up to at least 30 minutes after the procedure. After 1 hour the pain relieving effect has worn off.